In the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Original) A process for preparing a porous material having interconnected pores, comprising the following steps:

dissolving one or more kinds of bioresorbable polymers and a low molecular weight oligomer in an organic solvent to form a bioresorbable polymer solution; and

a coagulating step: exposing the bioresorbable polymer solution to a coagulant to form the porous material, wherein the low molecular weight oligomer is soluble in the coagulant, and the bioresorbable polymer is insoluble in the coagulant.

2. (Original) The process as claimed in claim 1, before the coagulating step, further comprising a step of making the bioresorbable polymer solution to form a pre-form.

3. (Original) The process as claimed in claim 2, wherein the pre-form forming step includes coating the bioresorbable solution onto a mold surface.

4. (Original) The process as claimed in claim 2, wherein the pre-form forming step includes pouring the bioresorbable solution into a container.

5. (Original) The process as claimed in claim 2, further comprising a step of drying the pre-form to partially or completely remove the organic solvent on the pre-form surface.

6. (Original) The process as claimed in claim 5, wherein the drying step makes the pre-form form a gel surface or a tack-free surface.

7. (Original) The process as claimed in claim 5, wherein the drying step is conducted in air at room temperature, by heating, in an oven, at a reduced pressure, or by radiation.

8. (Original) The process as claimed in claim 1, wherein the bioresorbable polymer has a molecular weight of 20,000 to 1,500,000.

9. (Original) The process as claimed in claim 1, wherein the bioresorbable polymer is polycaprolactone (PCL), polylactic acid (PLA), poly-L-lactide (PLLA), polyglycolic acid (PGA), poly-lactic-co-glycolic acid copolymer (PLGA copolymer), polycaprolactone-polylactic acid copolymer (PCL-PLA copolymer), polycaprolactone-polyethylene glycol copolymer (PCL-PEG copolymer), or mixtures thereof.

10. (Original) The process as claimed in claim 9, wherein the bioresorbable polymer is a mixture of PCL and PLA.

11. (Original) The process as claimed in claim 9, wherein the bioresorbable polymer is a mixture of PCL and PLGA copolymer.

12. (Original) The process as claimed in claim 1, wherein the low molecular weight oligomer has a molecular weight of 200 to 10,000.

13. (Original) The process as claimed in claim 12, wherein the low molecular weight oligomer has a molecular weight of 200 to 5000.

14. (Original) The process as claimed in claim 1, wherein the low molecular weight oligomer is polycaprolactone triol (PCLTL), polycaprolactone diol (PCLDL), polycaprolactone (PCL), polylactic acid (PLA), polyethylene glycol (PEG), polypropylene glycol (PPG), polytetramethylene glycol (PTMG), or mixtures thereof.

15. (Original) The process as claimed in claim 1, wherein the organic solvent for dissolving the bioresorbable polymer and the low molecular weight oligomer is N,N-dimethylformamide (DMF), N,N-dimethylacetamide (DMAc), tetrahydrofuran (THF), an alcohol, chloroform, dichloromethane (DCM), 1,4-dioxane, or mixtures thereof.

16. (Original) The process as claimed in claim 1, wherein the bioresorbable polymer is present in an amount of 5-70% weight fraction of the bioresorbable polymer solution.

17. (Original) The process as claimed in claim 16, wherein the bioresorbable polymer is present in an amount of 10-50% weight fraction of the bioresorbable polymer solution.

18. (Original) The process as claimed in claim 1, wherein the low molecular weight oligomer is present in an amount of 10-80% weight fraction based on the non-solvent portion of the bioresorbable polymer solution.

19. (Original) The process as claimed in claim 1, wherein the coagulant is water, an organic solvent, a mixture of water and an organic solvent, or a mixture of organic solvents.

20. (Original) The process as claimed in claim 19, wherein the coagulant is a mixture of water and an organic solvent and the organic solvent is present in an amount of 5-90% weight fraction.

21. (Original) The process as claimed in claim 20, wherein the organic solvent in the coagulant is an amide, a ketone, an alcohol, or a mixture thereof.

22. (Original) The process as claimed in claim 21, wherein the organic solvent in the coagulant includes a ketone and an alcohol.

23. (Original) The process as claimed in claim 1, wherein the step of exposing the bioresorbable polymer solution to a coagulant is performed at a temperature of 5°C to 60°C.

24. (Original) The process as claimed in claim 23, wherein the step of exposing the bioresorbable polymer solution to a coagulant is performed at a temperature of 10°C to 50°C.

25. (Original) The process as claimed in claim 1, after the bioresorbable polymer solution is exposed to the coagulant, further comprising washing the porous bioresorbable material in a washing liquid.

26. (Original) The process as claimed in claim 25, wherein the washing liquid is water, an organic solvent, a mixture of water and an organic solvent, or a mixture of organic solvents and the organic solvent in the washing liquid is a ketone, an alcohol, or a mixture thereof.

27. (Original) A process for preparing a porous material having interconnected pores, comprising the following steps:

dissolving one or more kinds of bioresorbable polymers and a low molecular weight oligomer in an organic solvent to form a bioresorbable polymer solution;

making the bioresorbable polymer solution to form a pre-form;

drying the pre-form to partially or completely remove the organic solvent on the pre-form surface; and

exposing the pre-form to a coagulant to form the porous material, wherein the low molecular weight oligomer is soluble in the coagulant and the bioresorbable polymer is insoluble in the coagulant.

35 U.S.C 103(a)

The Examiner is thanked for the thorough examination of the present application. The Office Action, however, rejected all claims 1-27 under 35 U.S.C 103(a) as allegedly unpatentable over Ma et al. (US 6,673,285 B2).

Applicant respectfully traverses the rejections for at least the reasons discussed below.

None of the references teach or suggest mixing pore former and bioresorbable polymer in an organic solvent.

Independent claims 1 and 27 recite:

> 1. A process for preparing a porous material having interconnected pores, comprising the following steps:
> ***dissolving one or more kinds of bioresorbable polymers and a low molecular weight oligomer in an organic solvent to form a bioresorbable polymer solution;*** and
> a coagulating step: ***exposing the bioresorbable polymer solution to a coagulant to form the porous material, wherein the low molecular weight oligomer is soluble in the coagulant, and the bioresorbable polymer is insoluble in the coagulant.***
>
> 27. A process for preparing a porous material having interconnected pores, comprising the following steps:
> ***dissolving one or more kinds of bioresorbable polymers and a low molecular weight oligomer in an organic solvent to form a bioresorbable polymer solution;***
> making the bioresorbable polymer solution to form a pre-form;
> drying the pre-form to partially or completely remove the organic solvent on the pre-form surface; and
> ***exposing the pre-form to a coagulant to form the porous material, wherein the low molecular weight oligomer is soluble in the coagulant and the bioresorbable polymer is insoluble in the coagulant.***

(*Emphasis added.*) Independent claims 1 and 27 patently define over the cited art of record for at least the reason that the cited art fails to disclose the features emphasized above.

Claims 1 and 27 each recite dissolving one or more kinds of bioresorbable polymers and a low molecular weight oligomer in an organic solvent to form a bioresorbable polymer solution and exposing the bioresorbable polymer solution (pre-form) to a coagulant to form the porous material. It is therefore clearly that the low molecular weight oligomer (pore former) and the bioresorbable polymer are mixed in an organic solvent.

The Office Action alleged that it would be "inherent in the process of Ma that pyridine would tend to dissolve at least some of the low molecular weight material, such as paraffin." Applicant disagrees. First, Applicant notes that the claims require more than this (as is clear from the emphasized language of the recited claims above). Further, such a rejection embodies a fundamentally misplaced understanding and application of the doctrine of inherency.

The Federal Circuit has clearly-established precedence to this legal concept. To this end, the undersigned respectfully directs the Examiner's attention to the decision of *Elan Pharms. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221 (Fed. Cir. 2002), in which the Federal Circuit reversed a finding of inherency by a district court. In this opinion, the Court of Appeals for the Federal Circuit emphasized:

> An anticipating reference "must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). When [a rejection] is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, it must be shown that the undisclosed information was known to be present in the subject matter of the reference. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749-50 (Fed. Cir. 1991). ***An inherent limitation is one that is necessarily present; invalidation based on inherency is not established by "probabilities or possibilities."*** *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999).

(*Emphasis added.*)

This discussion by the Federal Circuit is certainly nothing new. The law surrounding the doctrine of inherency has not changed for over 60 years. In fact, the Federal Circuit has repeatedly quoted the language from the 1939 decision *Hansgirg v. Kemmer*, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 U.S.P.Q. (BNA) 665, 667 (CCPA 1939)), which stated "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient."

The Manual of Patent Examining Procedure (M.P.E.P.) also embodies these requirements. Specifically, MPEP 2112, in part, states:

> The fact that a certain result or characteristic ***may*** occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.... To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in they thing described in that reference, and that it would be so recognized by persons of ordinary skill.

(*Emphasis in original*).

In contrast to these legal and procedural requirements, the Office Action has substituted independent judgment in place of the actual teachings of the cited references, in a manner that embodies clear (and improper) hindsight. In this regard, the Office Action has stated only that it is "inherent in the process of Ma that pyridine would tend to dissolve at least some of the low molecular weight material, such as paraffin." This is clearly a situation where, at best, such a teaching that may be consistent with the other teachings of the cited references, but is certainly not necessarily present. Such situations are specifically addressed in the M.P.E.P. and Federal Circuit precedent, and do not constitute proper teachings for supporting a rejection of the claimed subject matter, under the doctrine of inherency.

In contrast, the cited reference teaches **casting** biodegradable polymer solution onto a **3-D negative replica** of a desired macroporous architecture **formed from paraffin spheres (pore**